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The Conventional Ultrasonic Nebulizer Proved Inefficient in Nebulizing a Suspension

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ABSTRACT

A study was undertaken to compare the amount of nebulized budesonide suspension and nebulized terbutaline sulphate solution inhaled by healthy adult subjects when conventional jet and ultrasonic nebulizers were used. Ten healthy subjects (5 male; age range, 16–52 years) used two conventional nebulizers: the Spira Elektro 4 jet nebulizer (Respiratory Care Center, Hämeenlinna, Finland) and the Spira Ultra ultrasonic nebulizer (Respiratory Care Center) in a breath-synchronized mode with each drug. The amount of drug inhaled, the inhaled mass, was defined as the amount of drug deposited on a filter between the inspiratory port of the nebulizer and the mouthpiece. The amount of budesonide and terbutaline sulphate was determined by reversed-phase high-performance liquid chromatography. Single-dose respules were used (0.5 mg of budesonide and 5.0 mg of terbutaline sulphate), and nebulization time up to the defined gravimetric output was recorded. The inhaled mass of budesonide varied depending on the nebulizer used, whereas the inhaled mass of terbutaline was unaffected by the choice of nebulizer. The median inhaled mass of budesonide was 31.4% of the nominal dose (i.e., dose of drug in the respule per label claim) with the Spira Elektro 4 and 9.9% with the Spira Ultra, whereas the median inhaled mass of terbutaline was 50% with the Spira Elektro 4 and 52% with the Spira Ultra. It appears that a suspension is generally more difficult to nebulize than a solution and that the budesonide suspension should not be used in conventional ultrasonic nebulizers.

Key words: jet nebulizer, ultrasonic nebulizer, budesonide

INTRODUCTION

Conventional jet nebulizers driven by compressed air from electrical compressors have been used for the aerosolization of aqueous drug solutions since the beginning of the century.(1) In the 1960s, ultrasonic nebulizers were introduced for the same purpose.(2) These inhalation devices later became widely used for the treatment of asthma and chronic bronchitis due to the introduction of new drugs, specifically, β_2-agonists and anticholinergics in aqueous solutions.

In 1987, Godfrey et al.(3) reported on the effectiveness of an aqueous budesonide suspension for nebulization in an infant with severe oral steroid–dependent asthma. This first report was

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followed by a number of studies showing nebulized budesonide to be clinically effective in asthmatic infants, children, and adults at a nominal dose ranging from 250 μg administered once daily to 1000 μg administered two times daily.[4–7] In 1990, the budesonide suspension was approved for the treatment of asthma by jet nebulization.

A drug suspension consists of insoluble micronized particles dispersed in a liquid medium, often water. During nebulization of a drug suspension, the aerosol droplets are potential carriers of the solid drug particles provided that the water droplets are larger than the particles. When nebulizing a suspension, both the nebulizer's droplet size and the drug particle size distributions affect the output of drug. Jet nebulizers producing aerosols with large droplets therefore deliver more budesonide than do jet nebulizers with small droplets as shown in a comparison between the Pari LC Jet nebulizer (Pari-Werk GmbH, Starnberg, Germany) and Ventstream jet nebulizer (Medic-Aid Ltd, Bognor Regis, UK).[8] The primary particle size of micronized budesonide has been reported to be approximately 2.4 μm.[9]

There are limited data on the behaviour of suspensions in conventional ultrasonic nebulizers. Dahlbäck[10] presented preliminary *in vitro* results indicating that a solution of sodium chloride was more readily nebulized with a Pulmosonic ultrasonic nebulizer (DeVilbiss Health Care, Inc., Somerset, PA) than was a suspension of budesonide. Berlinski and Waldrep[11] showed that budesonide output was lower using ultrasonic nebulization compared with jet nebulization. There is, however, a lack of data on the amount of budesonide delivered to the patient in an ordinary clinical treatment situation, that is, the inhaled mass of budesonide.[12] During nebulization, the inhaled mass of drug (the amount of drug inhaled by the patient) is mainly a product of the nebulizer's drug output rate and the patient's duty cycle.[13] *In vivo* comparisons of the inhaled mass of the budesonide suspension and a solution of a β_2-agonist using conventional jet and ultrasonic nebulization are not currently available.

The aim of this study was therefore to compare conventional jet and ultrasonic nebulization of budesonide suspension and terbutaline sulphate solution using a filter technique for measurement of the inhaled mass[12] in healthy adult subjects.

MATERIAL AND METHODS

Study design

The study was designed as a randomized, crossover, single-center trial and was performed over 2 days in a clinical setting. The two nebulizers selected for the study were of a conventional design: a conventional jet nebulizer (Spira Elektro 4, Respiratory Care Center, Hämeenlinna, Finland) (Fig. 1A) and a conventional piezoelectrical ultrasonic nebulizer (Spira Ultra, Respiratory Care Center) (Fig. 1B). The nebulizers were charged with budesonide suspension (0.25 mg/mL^{-1}, 2 mL suspension; Astra Draco AB, Lund, Sweden) or terbutaline sulphate solution (2.5 mg/mL^{-1}, 2 mL solution; Astra Draco AB). Ten healthy subjects used a Spira Elektro 4 jet nebulizer and a Spira Ultra ultrasonic nebulizer

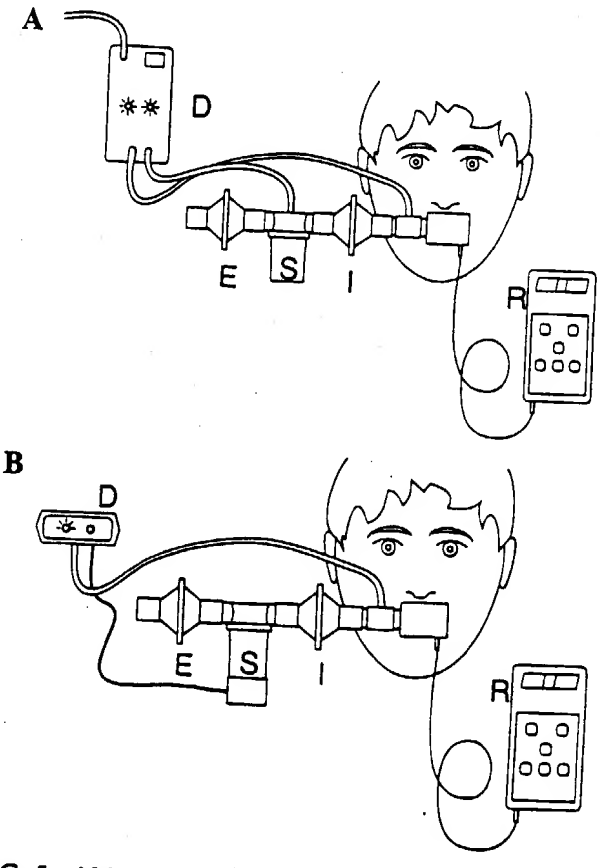

FIG. 1. Nebulizer setups. The inhalation port of the Spira jet nebulizer (S) was connected in series with an inspiratory filter (I), a Magtrac (R) respiratory flow sensor with rotameter, and a mouthpiece. An expiratory filter (E) was connected to the exhalation port of the nebulizer. The synchronizer (D) with flow sensor was (A) connected between the compressor and the nebulizer (Spira Elektro 4) or (B) added to the nebulizer setup (Spira Ultra).

in a breath-synchronized mode with each drug. The jet nebulizers were connected to a Spira compressor (Respiratory Care Center) and run at a flow of 7.5 L/min^{-1} through the nebulizers at a room temperature of ~20°C. The ultrasonic nebulizers were operated at a preset frequency of 2 MHz.

The nebulizers were used in a breath-synchronized mode in order to minimize the impact of breathing pattern variability on the inhaled mass of drug.[13] Breath synchronization was achieved through the use of inspiratory flow–activated electronic synchronizers (D, see Fig. 1A and B). The synchronizer was set to pulse compressed air through the jet nebulizer during the whole inspiration or to the synchronizer's maximum pulse time of 3 seconds. When the ultrasonic nebulizer was used, the synchronizer was set to activate the nebulizer during the whole inspiration or to the synchronizer's maximum pulse time of 2.5 seconds.

Drug output

The total output of solution and suspension from the nebulizer was determined gravimetrically. The weight of the nebulizer cup, including the nebulizer charge of drug, was measured before and during nebulization. During constant nebulization of budesonide suspension on the bench, the Spira jet nebulizer reached the sputtering phase when approximately 0.6 mL of suspension (0.6 g) remained in the nebulizer cup. The output of both the suspension and the budesonide was linear up to the sputtering phase. A similar *in vitro* test could not be performed on the bench with the ultrasonic nebulizer, as it could not be disconnected from the synchronizer and run in a constant output mode. Nebulization was therefore stopped for both the jet nebulizer and the ultrasonic nebulizer when 75% of the nebulizer charge had been nebulized. This meant that of a 2 mL budesonide suspension or terbutaline sulphate solution volume, 1.5 mL (1.5 g) left the nebulizer. The change in the weight of the nebulizer was tested at regular intervals throughout the nebulization process. When 1 mL of the nebulizer charge had been nebulized, the weight change was checked at shorter intervals to ensure a total output of 1.5 mL. The maximum nebulizer charge volumes are 20 mL for the Spira Elektro 4 and 18 mL for the Spira Ultra. Single-dose respules were used, and nebulization time up to the defined gravimetric output was recorded.

Inhaled mass

The inhaled mass of drug was defined as the amount of drug deposited on an inspiratory filter (Marquest MQ-303 viral filters, Marquest Medical Products, Inc., Englewood, CO) located between the mouthpiece and the nebulizer's inspiratory port. The amounts of drug aerosolized during expiration were deposited on an expiratory filter (see Fig. 1A and B). *In vitro* tests have shown that the Marquest filter can catch approximately 99.8% of the budesonide sucked through the filter.[14] The addition of the inspiratory filter to the nebulizer introduced an equipment dead space of approximately 30 mL which was equal to half of the filter housing volume. Budesonide was eluted from the filters with a water ethanol solution, whereas terbutaline was eluted with a sulphuric acid solution. The concentration and mass of budesonide and terbutaline were determined by high-performance liquid chromatography at the Analytical Chemistry Department of Astra Draco AB, Lund, Sweden.

Droplet size determination

The aerosol droplet size was characterized with a Malvern Mastersizer Model MS1000 (Malvern Instruments Ltd., Malvern, UK). Three conventional constant output Spira jet nebulizers were run continuously three times each with budesonide and three times each with isotonic saline. The mass median diameter (MMD) of the droplets was 3.7 μm (range 3.5–4.1 μm; SD = 0.2) with budesonide and 3.6 μm (range 2.7–4.2 μm; SD = 0.6) with isotonic saline. As the jet nebulizers showed no difference between budesonide and saline, two breath-synchronized Spira Ultra nebulizers were tested two times each charged only with budesonide in 0.7-second pulses during 6 seconds of measurement. The MMD was 5 μm (range 4.5–5.6 μm; SD = 0.5).

Subjects

Ten healthy adult subjects (5 male) were included. Their mean age was 39 years (range 16–52 years), their mean height was 169 cm

(range 158–178 cm), and their mean weight was 64 kg (range 52–75 kg). Their mean forced expiratory volume in 1 second and forced vital capacity were 107.7% (84.3–159.9) and 111.9% (85.1–149.5), respectively, of predicted normal values.[15] The study was performed in accordance with the principles stated in the Declaration of Helsinki and was approved by the local Ethics Committee of the Department of Allergic Diseases, Helsinki University Central Hospital, Helsinki, Finland.

The subjects were instructed to inhale during tidal breathing through mouthpieces connected to the nebulizers and used nose clips during the whole maneuver. The subjects' inspiration through the nebulizer was recorded throughout nebulization with a Magtrac II general purpose respiratory flow sensor (Ferraris Medical Ltd., London, UK) which updated the recorded inspiratory minute volume (V_I) every 20 seconds. Lung function measurements (i.e., forced expiratory volume in 1 second and forced vital capacity were performed with a Vitalograph Compact spirometer (Vitalograph Ltd, Buckingham, UK).

Statistics

The two drugs were compared within each nebulizer system using a nonparametric Wilcoxon rank-sum test. The same test was used for a comparison between the two nebulizer systems for each drug.

RESULTS

Inhaled mass of drug

The median inhaled mass of budesonide was 31.4% of the nominal dose with the Spira Elektro 4 and 9.9% with the Spira Ultra, whereas the median inhaled mass of terbutaline was 50.0% with the Spira Elektro 4 and 52.0% with the Spira Ultra (Table 1). The difference in the median inhaled mass between budesonide and terbutaline was statistically highly significant within each nebulizer system ($P < 0.001$, Fig. 2). For budesonide, the nebulizer system used had a statistically significant effect on the inhaled mass ($P < 0.001$, see Fig. 2), whereas for terbutaline, there was no statistically significant difference.

Inhaled mass as percentage of total drug output

A qualitative analysis of the inhaled mass in relation to the total drug output (i.e., sum of drug on inspiratory and expiratory filters) gives an estimate of the function of the breath synchronizer. When using a breath-synchronized nebulizer system, one would expect the inhaled mass to be close to 100% of the total drug output. The me-

TABLE 1. DATA ON AMOUNT OF DRUG ON FILTERS, TOTAL DRUG OUTPUT, GRAVIMETRIC OUTPUT, NEBULIZATION TIME, AND INSPIRATORY MINUTE VOLUMES

Variable	*Budesonide, Spira Elektro 4*	*Budesonide, Spira Ultra*	*Terbutaline, Spira Elektro 4*	*Terbutaline, Spira Ultra*
Inhaled mass (median and range as percentage of nominal dose)	31.4 (27.0–38.0)	9.9 (9.4–10.4)	50.0 (30.0–52.0)	52.0 (26.0–56.0)
Expiratory filter (median and range as percentage of nominal dose)	10.9 (8.0–14.0)	1.4 (0.6–2.0)	9.6 (7.6–16.4)	4.1 (1.6–5.8)
Total drug output (median and range as percentage of nominal dose)	42.8 (37.8–47.6)	11.0 (10.6–12.0)	61.2 (39.0–64.4)	56.8 (30.4–61.8)
Gravimetric output (median and range in milliliters)	1.55 (1.54–1.58)	1.50 (1.49–1.53)	1.50 (1.49–1.52)	1.50 (1.49–1.51)
Nebulization time (mean and range in minutes)	7.9 (6.0–9.5)	11.0 (9.0–12.6)	8.6 (6.8–10.7)	6.6 (5.4–8.4)
V_I in first minute (mean and range in liters)	10.5 (6.5–15.5)	11.5 (8.6–15.2)	12.7 (8.7–21.1)	12.0 (8.2–16.8)
V_I in last minute (mean and range in liters)	13.2 (8.9–17.7)	12.2 (7.2–17.0)	13.9 (8.9–22.0)	13.0 (10.3–16.5)

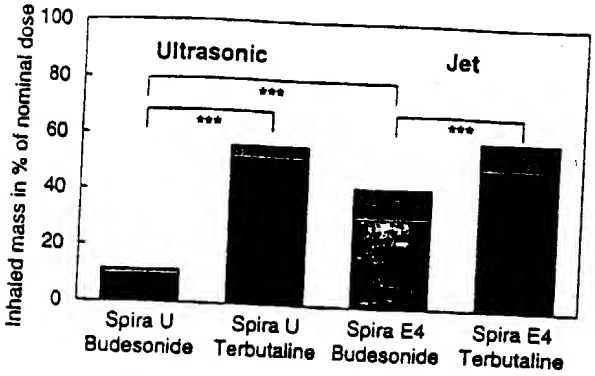

FIG. 2. The inhaled mass of drug (solid black) and the amount of drug wasted (gray grid) during expiration were expressed as percentages of the nominal dose of drug plotted for each nebulizer setup and drug. The results are given as median values. The difference in the median inhaled mass between budesonide and terbutaline was statistically significant within each nebulizer system ($P < 0.001$). For budesonide, the nebulizer system used had a statistically highly significant effect on the inhaled mass ($P < 0.001$), whereas for terbutaline, there was no statistically significant difference.

dian inhaled mass using the ultrasonic nebulizer was 87.5% of the total drug output for budesonide and 91.7% of the total drug output for terbutaline. When using the jet nebulizers, however, the median inhaled mass decreased as a percentage of the total drug output and was 75.8% for budesonide and 84.2% for terbutaline.

Inhalation technique and other variables

The V_I values for the first and last minutes of nebulization are displayed in Table 1. The results indicate that the subjects inhaled within approximately the same range of V_I through all four nebulizers. The amount of drug deposited on the exhalation filters, total drug ouput, gravimetric solution and suspension output, and nebulization times are also displayed in Table 1.

DISCUSSION

The study was designed to determine the inhaled mass of drug nebulized by conventional jet and ultrasonic nebulizers. The inhaled mass of nebulized drug was defined as the amount of drug deposited on filters located between the nebulizers and the subjects. Breath synchronization was mainly used to minimize the impact of the subjects' breathing pattern variability on the inhaled mass of drug.[13] Inspiratory time and nebulization time should have been approximately equal when using a breath-synchronized system. A change in the duty cycle would mainly have affected the nebulization time, as the time to reach an output of 1.5 mL would have required approximately the same total inspiratory time. The two brands of Spira nebulizers selected for the comparison were both designed as conventional T-piece nebulizers. As the T-piece design of the nebulizers was similar, the impact of a subject's breathing pattern (i.e., tidal volume, inspiratory flow, and duty cycle) should not have differed between the nebulizers. The inhaled mass of nebulized budesonide has previously been investigated in children[14] but not in adults; the inhaled mass of nebulized terbutaline sulphate has not been previously investigated using the filter technique.[12]

When using the ultrasonic nebulizer, the difference in inhaled mass between the budesonide suspension and terbutaline solution was approximately fivefold. This result is in agreement with preliminary *in vitro* results which indicated that a solution of sodium chloride was more readily nebulized than a suspension of budesonide with a Pulmosonic ultrasonic nebulizer.[10] The Pulmosonic ultrasonic nebulizer's droplet MMD was, however, reported to be 1 μm, whereas the diameter of the budesonide particles has been reported to be 2.4 μm.[9] The question remains as to whether the budesonide suspension could have been successfully nebulized if the ultrasonic nebulizer's droplet size had been more in agreement with the budesonide particle size, that is, closer to 3 μm. In the *in vitro* study by Berlinski and Waldrep,[11] the Aerosonic nebulizer's (DeVilbiss Health Care, Inc., Somerset, PA) droplet mass median aerodynamic diameter was reported to be 2.9 μm.[11] There was a four- to fivefold difference between the output of budesonide between the Aerosonic nebulizer and the Sidestream jet nebulizer (Marquest Medical Products, Inc., Englewood, CO) (mass median aerodynamic diameter = 3.6 μm) in that study. This is close to the threefold difference between the budesonide output from the Spira ultrasonic (MMD = 5.0 μm) and jet nebulizers (MMD = 3.7 μm) in the present study. The results from the present study and the *in vitro* results by Berlinski and Waldrep[11] indicate that the poor budesonide output is due to factors other than the conventional ultrasonic nebulizer's droplet size distribution.

Drug solutions and suspensions in the jet nebulizer cup have been shown to concentrate during use. Evaporation of solvent in the jet nebulizer has been claimed to be the major reason for the increase in concentration.[16,17] The evaporation of solvent has been shown to be related to both saturation of compressed air within the jet nebulizer and jet nebulizer design.[18] Dennis et al[18] did not find any evaporation of solvent when using a Microinhaler ultrasonic nebulizer (Vestric, Runcorn, UK), however, and reported a close correlation between aerosol output as determined by the fluoride tracer method and nebulizer weight loss. The results of the present study did, however, show that evaporation occurred during ultrasonic nebulization of terbutaline solution. Approximately 50% of the nebulizer charge of terbutaline was aerosolized compared with 75% of the solvent.

With the use of breath-synchronized nebulizers, the aerosolized drug should mainly be deposited on the inspiratory filter, and the amount deposited on the expiratory filter should be negligible. The amount of drug "wasted" to the expiratory filters was therefore surprisingly high, especially following jet nebulization. The waste of drug to the expiratory filters could mainly be attributed to two factors. The first factor is related to the ventilated dead space in the nebulizer and the filter housing. At the end of inspiration, part of the nebulizer and half of the filter housing are filled with aerosol which is deposited on the expiratory filter during expiration. The second factor is related to how fast the nebulizer stops the production of aerosol after cessation of the inspiratory flow over the flow sensor. The comparison of the two nebulizer systems showed that the Spira Ultra wasted less drug at the expiratory filter than did the Spira Elektro 4. The ventilated dead space was approximately the same in both nebulizer systems, indicating that the jet nebulizer produced slightly more aerosol after inspiration, which was deposited on the expiratory filter during expiration.

Nebulizers have been shown to vary in terms of inhaled mass of drug, total drug output, droplet size, and nebulization time.[19] There is a growing demand for well-defined nebulizer drug ouput characteristics for different drugs.[20] The characterization of nebulizers is usually performed *in vitro*, and current best practice requires that these *in vitro* tests mimic patients' breathing patterns.[20] This can be achieved with a number of pumps.[12,21,22] There is, however, no comparative study proving that any of the available pumps can accurately mimic the patient's breathing pattern and produce the same inhaled mass of drug as the patient. The *in vitro* results are therefore difficult to put into a clinical perspective. The filter technique used to measure inhaled mass *in vivo* may therefore be used to bridge *in vitro* and clinical results.

The results of the present study indicate that a solution of terbutaline and a suspension of budesonide behave rather differently in conventional jet and ultrasonic nebulizers. The inhaled mass of budesonide varied depending on the nebulizer used, whereas the inhaled mass of terbutaline sulphate was unaffected by the choice of nebulizer. In conclusion, it appears that a suspension is generally more difficult to nebulize than a solution and that the budesonide suspension should not be used in conventional ultrasonic nebulizers.

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